

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Safety Evaluation of Topical Application of Nano-Liposomal Form of Amphotericin B (Sinaampholeish) in comparison with placebo on Healthy Volunteers; Phase I Clinical Trial.

Protocol summary

Study aim

To evaluate the safety of SinaAmpholeish in a double-blind, randomized, phase 1 clinical trial in healthy human volunteers.

Design

A randomized controlled trial, parallel, double-blind with the sample size of 27 volunteers (left and right volar side of their forearm).

Settings and conduct

54 forearms of 27 healthy volunteers who are blinded to intervention groups are randomly assigned to the active group and receive topical Nano-liposomal amphotericin-B 0.4% on one side and receive placebo on the other side of their forearms.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy volunteer aged between 18-65 who are willing to participate in the study and signing the informed consent. Exclusion Criteria: The history of any diseases or illness, mental illness, participating in another trial concurrently

Intervention groups

Intervention group includes left or right sides of the volar side of forearms which topical Nano-liposomal amphotericin-B 0.4% (15-g tubes), Razak Laboratories Company was applied. Control group include the opposite side of participants forearm which only receive the placebo (vehicle of active drug).

Main outcome variables

Erythema, Pruritus, and other possible adverse reaction (by clinical exam or participants history)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081130001475N12**

Registration date: **2019-02-21, 1397/12/02**

Registration timing: **retrospective**

Last update: **2019-02-21, 1397/12/02**

Update count: **0**

Registration date

2019-02-21, 1397/12/02

Registrant information

Name

Ali Khamesipour

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8897 0657

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2012-06-13, 1391/03/24

Expected recruitment end date

2012-07-13, 1391/04/23

Actual recruitment start date

2012-07-13, 1391/04/23

Actual recruitment end date

2012-07-13, 1391/04/23

Trial completion date

2012-07-13, 1391/04/23

Scientific title

Safety Evaluation of Topical Application of Nano-Liposomal Form of Amphotericin B (Sinaampholeish) in

comparison with placebo on Healthy Volunteers; Phase I Clinical Trial.

Public title

"Safety Evaluation of Topical Application of Nano-Liposomal Amphotericin B (Sinaampholeish)"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy volunteer aged between 18-65 willingness to participate in the study and signing the informed consent form

Exclusion criteria:

Any disease or illness according to subject history
Mentally ill based on physician diagnosis participating in other concurrent trial

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **27**

More than 1 sample in each individual

Number of samples in each individual: **2**

The volar side of left or right forearm in each participant

Actual sample size reached: **27**

More than 1 sample in each individual

Actual sample size in each individual: **2**

The volar side of left or right forearm in each participant

Randomization (investigator's opinion)

Randomized

Randomization description

The master sheet of randomization was generated using online software before study conduct (Simple randomization method). Trial labels were put on the drugs. The Nano-liposomal formulation of amphotericin-B and its vehicle (as placebo) were prepared in identical tubes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Regarding the similar appearance of active drug and placebo, neither the volunteers nor the investigators were aware of the type of medication applied on each side.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Center for Research & Training in Skin Diseases & Leprosy, Tehran University of

Street address

No. 415, Taleghani St., Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

14166-13675

Approval date

2012-06-13, 1391/03/24

Ethics committee reference number

92-3450

Health conditions studied

1

Description of health condition studied

Cutaneous leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Erythema

Timepoint

Daily evaluation after the 1st day of intervention to 7th day.

Method of measurement

clinical exam

2

Description

Pruritus

Timepoint

Daily evaluation after the 1st day of intervention to 7th day.

Method of measurement

clinical Exam

Secondary outcomes

1

Description

Any reported adverse events

Timepoint

Daily evaluation after the 1st day of intervention to 7th day.

Method of measurement

Participants history

Intervention groups**1****Description**

Intervention group: Topical Nano-liposomal formulation of 0.4% Amphotericin B was applied on the left or right volar side of forearm twice a day for one week

Category

Treatment - Drugs

2**Description**

Control group: Topical placebo (vehicle of active drug) was applied on the left or right volar side of forearm twice a day for one week

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Center for Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Alireza Firooz

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Neglected Diseases Initiative

Full name of responsible person

Neglected Diseases Initiative (DNDi)

Street address

15 Chemin Louis-Dunant 1202 Geneva Switzerland

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dndi@dndi.org

Web page address

https://www.dndi.org/

Grant name

Safety Evaluation of Topical Application of Nano-Liposomal Form of Amphotericin B (Sinaampholeish) on Healthy Volunteers; Phase I Clinical Trial

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Neglected Diseases Initiative

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

Country of origin**Type of organization providing the funding**

Industry

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooze

Position

Profosser

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Prof./PhD

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Khamesipour

Position

professor

Latest degree

Ph.D.